# Evaluation of an innovative antimicrobial surgical glove technology to reduce the risk of microbial passage following intraoperative perforation

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***Background:*** Surgical gloves provide a protective barrier for patients and members of the surgical team. Although glove integrity is important in an era of blood-borne pathogens, little data exist on bacterial passage after glove perforation. This study evaluated the impact of antimicrobial surgical gloves in reducing microbial passage after glove puncture in a model of wound contamination.

***Methods:*** *Staphylococcus aureus* (ATCC 6538) and *Brevundimonas diminuta* (DSM 1639) were used to prepare a standardized suspension for testing bacterial passage after glove puncture in volunteers wearing single-layer gloves (group A), double-layer gloves (group B), or antimicrobial trilayer gloves (group C). After exposure periods of 5, 10, 30 and 45 minutes, the outer test gloves were removed and microbial passage was measured on the inner surface of the base gloves. Multiple repetitions (5 or 6) were performed at each sampling time.

***Results:*** Microbial passage at 5-, 10-, 30-, and 45-minute exposures were analyzed both separately and combined (5 and 10 minutes and 30 and 45 minutes). No difference was observed in microbial passage between group A and group B at the 10-, 30-, and 45-minute exposures for *S aureus*, whereas a significant reduction in microbial passage was observed in group C compared with group A ($P \leq .05$ to $< .005$) at the 5-, 30-, and 45-minute exposures for both *S aureus* and *B diminuta*. When timed groups were combined (5 and 10 minutes and 30 and 45 minutes), a significant reduction ($P \leq .01$ to $\leq .005$) in microbial passage of *S aureus* and *B diminuta* was observed in group C compared with both group A and group B.

***Conclusion:*** These findings represent the first evidence that microbial passage across surgical gloves can be reduced significantly using an innovative antimicrobial glove technology.

***Key Words:*** Chlorhexidine gluconate; quaternary ammonium salts; microperforation; surgical site infection; elastomeric antibacterial surgical gloves.

Sterile surgical gloves play a dual role during the intraoperative period, protecting the patient against contaminating hand flora and members of the operative team against blood-borne fluid pathogens, such as human immunodeficiency virus (HIV) and hepatitis C virus (HCV). However, studies have suggested that glove

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perforation rates range from 16% to >60% in selected surgical procedures, including gastrointestinal, cardiothoracic, orthopedic, obstetric, and gynecologic.[1-5] It has been suggested that during surgery, manipulation of abrasive and cutting objects and associated mechanical stress generate damage leading to microperforations, threatening the integrity of the glove barrier and allowing bacterial migration across the composite surface of the surgical glove.[6] The rate of microperforation has been shown to increase over time, calling into question how often members of the surgical team should change gloves, especially during long complex surgical procedures.[5]

Historically, the risk of transmission of HIV and HCV after a sharps injury in the operating room has led surgical practitioners to adopt appropriate interventional strategies, such as double-gloving for high-risk cases or when exposure to blood or body fluid places the surgical team at risk. A recent Cochrane collaborative review examined 31 clinical trials involving 8 selected surgical disciplines associated with both low-risk and high-risk procedures and found that although

double-gloving afforded greater protection to the inner layer against microperforation injury compared with single-gloving, there was no evidence that double-gloving reduced the risk of postoperative surgical site infection.[7] Given that most of the studies reviewed were not powered to discern a difference in infection rate, as well as the disparaging heterogeneity of the studies included in the analysis, it is not surprising that the authors were unable to assess the infection prevention benefit of double-gloving versus single-gloving. The relationship between glove integrity and the intraoperative passage of bacteria from patient (contaminated field) to surgeon or vice versa remains an unresolved question in terms of both risk and clinical impact. In the present investigation, we used an in vitro model of gross wound contamination to evaluate microbial passage through a conventional single-thickness latex glove, a double-thickness surgical glove, and an innovative trilayer antimicrobial surgical glove in which the middle layer contains an antimicrobial agent.

## MATERIALS AND METHODS

### Study subjects

The investigation was reviewed and approved by the Institutional Human Subjects Committee, and all volunteers provided informed consent before participation. A total of 34 volunteers were randomized into the 3 study groups identified below. Before donning study gloves, each participant performed skin antisepsis (for 90 seconds, in accordance with the manufacturer's recommendation) using an ethanol-based hand disinfectant (Bode Chemie Hamburg; Medline Industries, Mundelein, IL). After disinfection, skin flora of each hand (fingertips and palm) was analyzed. None of the test subjects exhibited bacterial growth on the test areas (ie, no growth after 48 hours of cultivation). Any individuals found to have a positive bacterial culture would have been excluded from the study analysis.

### Surgical test gloves

Four types of sterile surgical gloves were used in the in vitro study: group A, controls (n = 10), single-layer latex, powder-free, 225 μm thick (Semperit Technische Produkte, Vienna, Austria; group B (n = 12), double-layer latex, powder-free, 450 μm thick (Hutchinson Sante, SNC, Paris, France); group C (n = 12), integrated three-layer antimicrobial synthetic (thermoplastic elastomer), 500 μm thick (Hutchinson Sante); and a conventional latex surgical glove, 340 μm thick (ANSELL, Richmond, Australia), that was used as the base glove for evaluating microbial quantitative recovery after bacterial passage. The trilayer antimicrobial glove used in group C consisted of two boundary layers

separated by an antimicrobial middle layer in a droplike compartment (Fig 1). The antimicrobial was composed of chlorhexidine digluconate, didecyl dimethyl ammonium chloride salt, and benzalkonium chloride salt in a polyethylene glycol diluent. This disinfectant solution has been shown to be active against enveloped virus particles and selective gram-positive and gram-negative bacteria. Figure 1 illustrates the structural components of the trilayer antimicrobial surgical glove.

### Simulated contaminated field and test protocol

Two contaminated solutions were prepared for testing, one containing *Staphylococcus aureus* (ATCC 6538) and the other containing the test organism, *Brevundimonas* (formerly *Pseudomonas*) *diminuta* (DSM 1639). The *S aureus* is a standard laboratory reference strain used routinely for in vitro susceptibility studies, whereas because of its size, *B diminuta* is routinely used as a standard organism to validate the efficacy of sterilizing-grade membrane filters (0.2 μ). Both strains were recovered from frozen stock. After determination of purity, the organisms were inoculated to caseine peptone broth and incubated overnight at 35°C. Overnight cultures were adjusted to a concentration of 7.0 $\log_{10}$ cfu/mL in a final test volume of 3 L.

Before donning the study gloves, each participant donned a sterile latex (single-layer) indicator glove on each hand. Before the study gloves were applied, 4 punctures were made in each glove using a 20-gauge needle, 2 each (1 cm apart) in the distal medial thumb and index finger. Care was taken to avoid puncturing the base latex indicator glove. Once the study gloves were donned, both hands were immersed into a 5-L basin containing 3 L of contaminated broth (with *S aureus* or *B diminuta*) for a period of 5, 10, 30, or 45 minutes. While his or her hands were in the basin, the participant was asked to periodically (several times a minute) flex the hands, kneading the bottom of the basin to create pressure or stress on the tips of the gloved fingers. This process was repeated for all 3 study gloves at each specified time interval.

After each test period, the study gloves were carefully removed so as not to contaminate the external surface of the base latex glove. The base gloves were aseptically removed, both thumbs and index finger segments were inverted and filled with 25 mL of physiological saline and gently massaged for 30 seconds, and 100 μL of the solution was plated to Columbia agar containing 5% sheep's blood (Oxoid, Wesel, Germany) and incubated at 35°C for 48 hours. A total of 5 replicate samples were plated per sample interval for group A, whereas 6 replicate were plated for groups B and C in the *S aureus* challenge. A total of 5 replicates were plated for each time interval in groups A, B, and C
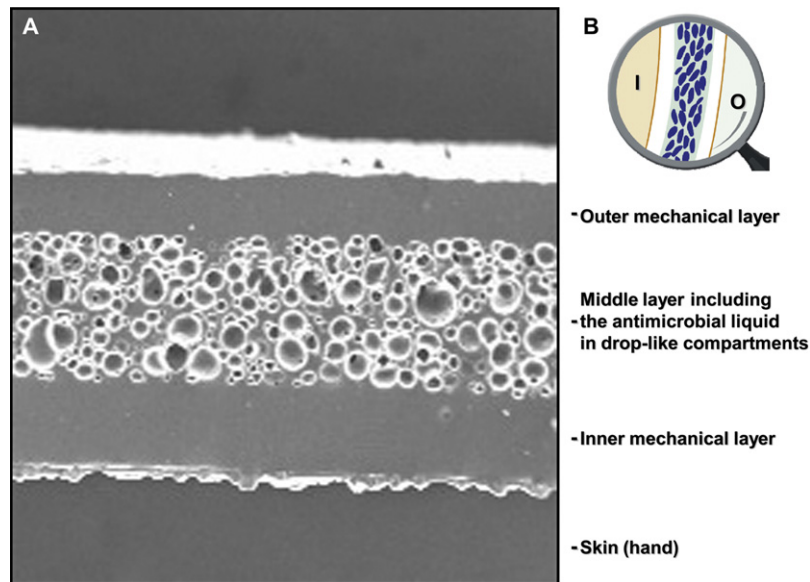
**Fig 1.** (A) Microscopic picture of trilayer surgical glove showing middle layer containing drop-like mixture of chlorhexidine and quaternary ammonium salts. (B) Artist rendition of trilayer surgical glove demonstrating inner (I) and outer (O) surfaces adjacent to elastomeric boundary layers sequestering the active antimicrobial droplet layer.

in the *B diminuta* Challenge. Mean microbial recovery was expressed as cfu/mL, and species recovery was validated by colony morphology, Gram staining, and biochemical characteristics (VITEK system; Biomerieux, Nurtingen, Germany).

### Statistical analysis

The Mann-Whitney *U* test (nonparametric) was used to analyze the differences in microbial passage among the 3 independent study groups. Analyses were performed using MINITAB (MINITAB Inc, State College, PA).

### RESULTS

The resultant microbial passage observed after right-left glove perforation at 5, 10, 30 and 45 minutes did not exhibit a normal distribution; thus, the comparative data sets in groups A, B, and C were analyzed nonparametrically. The initial study model was designed to detect microbial passage over 4 separate time intervals after glove puncture: 5, 10, 30, and 45 minutes. Right-hand and left-hand microbial passage was recorded separately; however, in each group, no significant difference were observed in microbial recovery between the right and left gloved hands, and so the right hand and left hand observations were combined for analysis among groups A. B, and C. Table 1 reports the mean microbial passage after glove perforation in groups A, B, and C for both *S aureus* and *B diminuta*. Compared with group A, group B ($P \leq .01$) and group C ($P \leq .005$) demonstrated a significant reduction in microbial passage after 5 minutes postexposure to the contaminant (Table 1). However, no significant difference between group A and group B was noted at 10, 30, or 45 minutes postexposure. No significant difference in microbial passage was observed between group C and group A at 10 minutes postexposure; however, a significant reduction in microbial passage in group C compared with groups A and B was seen at 30 minutes ($P \leq .05$) and 45 minutes ($P \leq .05$) postexposure. In general, a 2- to 3-log passage was observed in groups A and B, ranging from 15.3 cfu/mL (group B, at 5 minutes postexposure) to a mean of 572 cfu/mL (group A, at 45 minutes postexposure), whereas the mean microbial passage in group C ranged from 0.7 cfu/mL at 10 minutes postexposure to 41.5 cfu/mL at 45 minutes postexposure, representing <1- to 2-log passage postexposure. No significant difference was observed in mean microbial passage between groups A and B at 5, 10, and 30 minutes postexposure with *B diminuta* (Table 1). A significant reduction in microbial passage was noted at 45 minutes postexposure in group B ($P \leq .01$) compared with group A. A significant reduction in microbial passage was documented in group C compared with groups A and B at 5 minutes ($P \leq$ .01), 30 minutes ($P \leq .05$), and 45 minutes ($P \leq .05$) postexposure. No significant difference was observed at 10 minutes postexposure in group C compared with either group A or group B. Mean microbial passage increased by >10-fold over time in group A (range, 32-417 cfu/mL), whereas fewer organisms were recovered postexposure in group B (range, 42.7-120 cfu/mL) over the 4 timed intervals. Mean microbial passage (recovery) in group C ranged from a low of 1.0 cfu/mL at

**Table 1.** Mean microbial recovery (cfu/mL) at 5, 10, 30, and 45 minutes postexposure (right/left glove) to simulated wound contamination

| Exposure | Glove group* | | | | |
| --- | --- | --- | --- | --- | --- |
| | Group A | Group B | P | Group C | P |
| MSSA | | | | | |
| 5 minutes | 531 | 15.3 | ≤.01 | 1.7 | ≤.05 |
| 10 minutes | 48.7 | 344 | NS | 0.7 | NS |
| 30 minutes | 265 | 199 | NS | 7.6 | ≤.05 |
| 45 minutes | 572 | 506 | NS | 41.5 | ≤.05 |
| *B diminuta* | | | | | |
| 5 minutes | 39 | 77.5 | NS | 1.0 | ≤.01 |
| 10 minutes | 32 | 58.8 | NS | 7.7 | NS |
| 30 minutes | 182 | 120 | NS | 17.5 | ≤.05 |
| 45 minutes | 417 | 52.7 | ≤.01 | 1.6 | ≤.005 |

MSSA, methicillin-sensitive Staphyloccocus aureus; NS, not significant (*P* > .05).
*For MSSA: group A, n = 10; group B, n = 12; group C, n = 12; for *B diminuta*, group A, n = 10; group B, n = 10; group C, n = 10.

**Table 2.** Mean microbial recovery (cfu/mL) at 5 and 10 minutes and 30 and 45 minutes postexposure (right/left glove) to simulated wound contaminations

| Exposure | Glove group* | | | | |
| --- | --- | --- | --- | --- | --- |
| | Group A | Group B | P | Group C | P |
| MSSA | | | | | |
| 5 and 10 minutes | 292 | 180 | ≤.05 | 1.4 | ≤.005 |
| 30 and 45 minutes | 418 | 351 | NS | 24.5 | ≤.005 |
| *B diminuta* | | | | | |
| 5 and 10 minutes | 35.6 | 67.7 | NS | 4.4 | <.01 |
| 30 and 45 minutes | 299 | 86.5 | NS | 9.6 | ≤.005 |

MSSA, methicillin-sensitive Staphyloccocus aureus; NS, not significant (*P* > .05).
*For MSSA: group A, n = 10; group B, n = 12; group C, n = 12; for *B diminuta*, group A, n = 10; group B, n = 10; group C, n = 10.

5 minutes postexposure to 17.5 cfu/mL at 30 minutes postexposure.

Because of the short intervals between the 4 time groups, the 5- and 10-minute observations and the 30- and 45-minute observations in microbial passage were combined for a separate analysis. Table 2 documents the combined findings for groups A, B, and C. A significant reduction ($P ≤ .05$) in mean microbial passage of *S aureus* was observed between groups A and B at the combined 5- and 10-minute time interval, but not at the combined 30- and 45-minute interval. A significant reduction in *S aureus* passage was noted at both the 5- and 10-minute ($P ≤ .005$) and 30- and 45-minute intervals ($P ≤ .005$) in group C compared with groups A and B. No significant difference in *B diminuta* passage was noted between group A and group B at either the 5- and 10-minute or 30- and 45-minute combined time intervals (Table 2); however, a significant reduction in *B diminuta* passage was observed at both the 5- and 10-minute ($P ≤ .01$) and 30- and 45-minute ($P ≤ .005$) combined time intervals in group C compared with groups A and B.

## DISCUSSION

Glove perforation and sharps injuries are common occupational hazards for surgical practitioners. Although approximately 99% of surgeons indicate that they have experienced a needlestick injury, more than 50% of these injuries go unreported.[8,9] The single-layer surgical glove should be viewed as a very thin (sometimes <0.25 mm thick) rubber-based membrane, which is repeatedly exposed to abrasive or cutting-like surfaces during surgery. In many cases, the glove may be punctured in such a manner that little if any penetration of the dermis occurs, and thus the perforation is not perceived by the wearer. Studies

have estimated that double-gloving can reduce the risk of intraoperative blood exposure by 6-fold to 13-fold.[10-12] Thus, double-gloving is viewed as an effective "barrier enhancement" strategy, especially when the perforation is caused by a sharps object with a rather simple geometry, such as a suture needle. However even when double gloves are used, tiny punctures on the inner glove are still be observed in 4% of surgical procedures.[13] A review of the recent literature suggests that glove perforation occurs within all surgical disciplines, with frequency rates ranging from 19% in major elective gynecologic surgeries to a high of 78% during emergent surgical procedures.[1,14] Because of the perceived rate of unnoticed glove perforation, some surgical practitioners have suggested routine glove changes within a 2-hour cycle.[4]

An unresolved question involves the role of glove perforation in contamination of the surgical field. Several investigations have attempted to address the impact of perioperative environmental contamination as a risk factor for postoperative infection. The role of environmental contamination during selected orthopedic surgical procedures has been well documented in the literature;[15,16] however, to date few studies have addressed the impact of glove perforated as an etiologic factor in acquisition of postoperatjve surgical site infection. Eklund et al[17] noted that in cardiothoracic surgical procedures, glove perforation is greatly influenced by the duration of surgery, with the breakage rate of surgical gloves increasing from 30% in procedures lasting 3 hours or less to 65% in cases lasting longer than 5 hours. That study was not sufficiently powered to assess the risk of glove failure with increased postoperative infection, however. The authors did point out that although changing a torn or damage surgical glove is a common intraoperative practice, the surgeon often becomes aware of the breech in barrier protection by microperforations only after observing traces of blood on the hands after glove removal (author's [C.E.E.] personal observation). In the Eklund group's study, the

investigators noted that more than 50% of the surgeons' hands were recolonized by the end of the cases, and, depending on the size of the microperforation, it is conceivable that hand flora could contaminate the wound bed or a biomedical device at the time of implantation.[17] A study conducted in patients undergoing total hip arthroscopy found that regular glove changes significantly reduced the risk of glove perforation and in turn reduced the incidence of wound contamination.[18] A study conducted at Vanderbilt University involving more than 800 pediatric patients undergoing cerebrospinal shunt placement found that a shunt infection rate of 15.2% when surgical personnel wore single-layer surgical gloves, compared with 6.7% when double-gloving was used.[19] Interestingly, this was not a novel finding, but had been reported in 2001 by Kulkarni et al,[20] who proposed that shunt infection after placement might be due to defects in the integrity of the traditional single-layer surgical gloves worn by the surgical personnel. Pediatric shunt infections are a frustrating acute complication in patients undergoing cerebrospinal fluid shunt therapy, and intraoperative contamination is universally viewed as the primary etiologic factor associated with this adverse outcome. A recent study conducted in more than 4,000 general, vascular, and trauma surgical patients found that glove perforation was associated with a higher likelihood of surgical site infection when there was failure to administer timely and appropriate antimicrobial prophylaxis, suggesting that the presence of appropriate antibiotic tissue/fluid concentrations during surgery was protective against wound contamination after surgical glove failure.[21] That study clearly documented a sentinel clinical relationship between glove integrity, antimicrobial prophylaxis and postoperative surgical site infection. A study published in 2010 found that bacterial passage after glove puncture from the operative site occurred in approximately 5% of surgical gloves worn during selective abdominal procedures.[22] The investigators found that outer glove perforation occurred 21.1% of the time, whereas inner glove perforation was noted in 14.8% of the procedures. The frequency of perforation was directly correlated with the duration of surgery (range of time studied, 90-255 minutes).[22] Although that study was not designed nor powered to address the impact of glove perforation on surgical site infection, the results confirm that microperforation occurs unbeknownst to the wearer and can be a portal for bacterial passage.

In the present investigation, we evaluated the impact of glove microperforation on the passage of two strains of bacteria using a simulated model of "gross wound contamination" in volunteers wearing a single-layer, double-layer, or synthetic trilayer antimicrobial glove on both the right and left hands. The

3 independent groups were exposed to a contaminated model system for 5, 10, 30, and 45 minutes, after which microbial passage was assessed by sampling the inner surface of the test material. Compared with both single-layer and double-layer latex gloves, the antimicrobial surgical glove significantly reduced microbial passage of *S aureus* and *B diminuta* after 5, 30, and 45 minutes (range, $P \leq .05$ to $\leq .005$) of exposure to the contaminated broth. Compared with the trilayer antimicrobial glove, use of a double-layer glove appeared to provide limited protective benefit against microbial passage after glove perforation. When the study intervals were combined (5 and 10 minutes and 30 and 45 minutes) to evaluate a broader exposure time, a significant protective benefit was observed with the trilayer antimicrobial glove (group C) compared with either single-layer (group A) or double-layer (group B) latex groups against passage of both *S aureus* ($P \leq$ .005) and *B diminuta* (range, $P \leq .01$ to $\leq .005$).

Our study has several limitations. First, the duration of exposure was limited to a maximum of 45 minutes, which is similar to the time required to complete a hernia repair, open breast biopsy, or cholecystectomy. Further studies are warranted documenting the benefit over an extended time interval (1-5 hours). Second, the original study design called for a total of 4 puncture injuries per glove using a 20-gauge needle; larger-gauge injury or glove perforation with a geometrically complex sharps device should be evaluated in future studies. The present study measured microbial passage after glove perforation from an outer boundary contaminated field to the inner glove surface (thumb and index finger). To date, little is known about the dynamics of reverse migration (hand to outer boundary) after multiple glove perforations. Although the "surgical hand scrub" with an appropriate antiseptic agent is a standard practice prior to all surgical procedures, its has been hypothesized that microbial transit across the perforated surgical glove is a likely source of wound and biomedical device–related contamination.[18-22] Finally, the current findings call for additional "reverse-phase" studies, which document microbial passage from the surgical practitioner's hands outward and the benefit of an integrated antiseptic glove technology to reduce the risk of microbial passage during lengthy (>3 hours) surgical procedures.

This innovative antimicrobial surgical glove technology involves a middle layer containing an antimicrobial agent (chlorhexidine and quaternary ammonium salts) sequestered within droplets (Fig 1) sandwiched between two elastomeric boundary layers. On glove puncture, the antimicrobial agent is released (squeeze-out) from the middle layer, resulting in the deposition of active antimicrobial agent at the site of injury or puncture. This release is limited to the local site of injury and does not dissipate the antimicrobial activity elsewhere in the

glove.[23] Therefore, theoretically the glove's utility is not limited to a single perforation, but rather provides a protective benefit after multiple perforations, which often occur unbeknownst to the surgical practitioners, especially during long surgical procedures. In addition, because the antimicrobial droplets are sequestered between two elastomeric boundary layers, in the absence of injury there is no chronic exposure of the substance to the skin surface, reducing the risk of skin sensitivity over time. Two recent laboratory studies using herpes simplex type 1 virus, bovine viral diarrhea virus, and feline immunodeficiency virus as surrogate viruses for HCV and HIV demonstrated a significant reduction (81%-85%) in the number of transmitted viruses after percutaneous puncture of the trilayer antimicrobial glove using a hollow-bore needle compared with a double-layer latex glove.[24,25] These studies clearly document the benefit of this surgical glove as an protective antiviral barrier when exposed to high-risk (ie, HIV and HCV) surgical patient populations.

The present investigation represents the first study to document the impact of an antimicrobial surgical glove technology to reduce the risk of bacterial passage after glove perforation compared with conventional single- and double-layer surgical gloves. Although glove perforation as an etiologic factor in the development of postoperative surgical site infection is a matter of continued debate, an active antimicrobial delivery system incorporated within a trilayer surgical glove would appear to have several obvious intrinsic benefits compared with traditional surgical gloves, including:

- Reduced risk of exposure to body fluid– and blood-borne pathogenic agents in high-risk patients
- Reduced risk of wound and biomedical device contamination at the time of implantation
- Active barrier protection in short- and long-duration surgical procedures
- A single protective glove component rather than requiring acclimation to two different- sized surgical gloves.

A reduction in selected surgical site infections is currently mandated by both governmental (eg, Center for Medicare and Medicaid Services) and other regulatory bodies (eg, the Joint Commission). These preliminary studies of an innovative surgical glove technology warrant further investigation to validate its benefit as an effective strategy for reducing the risk of postoperative surgical site infection.

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